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EXAMINER	
DEVI, SARVAMANGALA J N	
ART UNIT	PAPER NUMBER
1645	

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15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/522,752	Applicant(s) ANDREW ET AL.	
	Examiner Jessica H. Roark	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 January 2002 and 21 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *46-50 and 76-216* is/are pending in the application.

4a) Of the above claim(s) *76,77,86-88,91,92,96-98,110,115,116 and 202-216* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *46-50,78-85,89,90,93-95,99-109,111-114,117-146 and 148-201* is/are rejected.

7)☒ Claim(s) *147* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 March 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8-9, 11* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's amendments, filed 1/17/02 and 10/21/02 (Paper Nos. 13 and14), are acknowledged.
Claims 1-45 and 51-75 have been canceled.
Claims 78-216 have been added.
Claims 46-49 have been amended.
Claims 46-50 and 76-216 *are pending in the instant application..*

2. Applicant's election with traverse of Group VI in Paper No. 13 is acknowledged. The traversal is on the grounds that there were errors in the original restriction requirement (Paper No. 4).

Upon review of the original restriction requirement, it does appear that claims 60 and 61 belong in Group I rather than in Group VII. In addition, the subject matter of claims 76 and 77 also appears to belong in Group I as the immunoconjugate and antibody fusion protein are specific for GPR-9-6.

Therefore, the restriction requirement of Paper No.4 is WITHDRAWN to the extent that claims 60 and 61, as now represented by pending claims 215 and 216, are removed from Group VII and claims 76-77 are removed from group VII. The remainder of the restriction requirement of Paper No. 4 is hereby incorporated by reference.

The organization of Groups I, V and VII has been revised as follows:

I (revised). Original claims 1-4, 51-53, 60-61, 76-77 and 215-216, drawn to an antibody to GPR-9-6, isolated cells producing said antibody, immunoconjugates and fusion proteins of said antibody, and kits comprising, classified in Class 530, subclasses 387.3, 388.22 and 391.1; and Class 435, subclasses 334 and 810.

V (revised). Original claims 32-45 and 71-75, drawn to a method of treating a subject using an antagonist of GPR-9-6, classified in Class 424, subclass 143.1.

VII (revised). Original claims 54-59, 62-68 and 70, drawn to an antibody which binds TECK, cells producing said antibody, and kits comprising, classified in Class 530, subclass 388.23; and Class 435, subclasses 335 and 810.

THE SUBJECT MATTER OF CLAIMS 215-216 (original claims 60 and 61), 76 and 77, IF PROSECUTED IN A DIVISIONAL APPLICATION, SHOULD BE INCLUDED WITH THE SUBJECT MATTER OF GROUP I. Applicant is reminded that where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971).

In view of the present election, claims 76-77 and 215-216 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.

3. Upon further consideration of the claims, an additional Species Election with respect to original Group VI is required as set forth below.

Species Election

4. Claims 47, 89, 108 and 202 are generic to a plurality of disclosed patentably distinct species comprising the "agent" which "modulates" a function of GPR-9-6. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. During a telephone conversation with Robert H. Underwood on 10/22/02 a provisional election was made with traverse to prosecute an agent which *inhibits* a function of GPR-9-6 and is an *antibody to GPR9-6*. Affirmation of this election must be made by applicant in replying to this Office action.

6. Applicant is advised that the search has been extended to encompass an agent which *promotes* a function of GPR-9-6 and is the *chemokine TECK*. Claims 86-88, 91-92, 96-98, 110, 115-116 and 202-214 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected species.

7. *Claims* 46-50, 78-85, 89-90, 93-95, 99-109, 111-114 and 117-201 *are under consideration.*

Drawings

8. Formal drawings have been submitted which fail to comply with 37 CFR 1.84.
Please see the enclosed form PTO-948.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

A. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. *The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.*

B. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

*Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.*

Priority

9. Applicant's claim for domestic priority under 35 U.S.C. 120 is acknowledged.

Parent application USSN 09/266,464 issued on 12/11/01 as U.S. Pat. No. 6,329,159. The "related Application" information should be updated to reflect this.

Parent USSN 09/266,464 does not appear to provide adequate written support for the GPR96-1 antibody recited in instant claims 82-83, 135-136, 151-152, 172, 192, nor for the anti-TECK antibodies 16.3.1 and 11.3.1 recited in instant claims 207-210.

IDS

10. Applicant's IDSs, filed 8/14/00, 1/4/02 and 4/26/02 (Paper Nos. 8-9 and 11), are acknowledged.

Specification

11. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention *to which the claims are directed.*

12. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

Claim Rejections - 35 USC § 112 first paragraph

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 46-50, 78-85, 89-90, 93-95, 99-109, 111-114, 117-146 and 148-201 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The following *written description* rejection is set forth herein.

The claims recite either singly or in combination "GPR-9-6", "mammalian GPR-9-6", an "agent which binds" GPR-9-6, and a "ligand" of GPR-9-6 as part of the invention.

The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 3rd column).

However, there does not appear to be an adequate written description in the specification as-filed of any essential structural feature common to molecules that are "GPR-9-6" or "mammalian GPR-9-6". Neither does there appear to be an adequate written description in the specification as-filed of any essential structural feature common to molecules that are an "agent which binds" GPR-9-6 or "ligands" of GPR9-6 that identifies molecules as having the function of binding GPR9-6.

The specification discloses the human GPR-9-6 protein of SEQ ID NO:2 and bound by the 3C3 and GPR96-1 antibodies. However, the instant claims are drawn to a large genus of GPR-9-6 molecules expressed by a cell from either any species (a "GPR9-6), or any mammal (a "mammalian GRP9-6"). There does not appear to be any particular structure that must be shared by polypeptides in order to identify them as a "GPR-9-6" or a "mammalian GPR9-6". Thus the disclosure of a single species does not appear to provide adequate written support for the genus.

Similarly, the specification discloses a single chemokine ligand of GPR-9-6: TECK (see page pages 71-72 of the specification). However, the genus of molecules encompassed by the term "ligand" or "agent that binds thereto" is very large and includes not only chemokines and antibodies to GPR-9-6, but any molecule or pathogen which can bind GPR-9-6. Thus the disclosure of a single species of chemokine ligand and an "agent which binds thereto" that is an antibody does not appear to provide an adequate written description of the genus of "ligands of GPR-9-6" or "agent which binds thereto".

Consequently, Applicant was not in possession of the instant claimed invention. See Regents of the University of California v. Eli Lilly and Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). Adequate written description of genetic material "'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention." Id. 43 USPQ2d at 1404 (quoting Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606). The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter of the claim. Id. 43 USPQ2d at 1406. A description of what the genetic material does, rather than of what it is, does not suffice. Id.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Alternatively, Applicant is invited to point to clear support or specific examples of the claimed invention in the specification as-filed.

15. Claims 46-50, 78-85, 89-90, 93-95, 99-109, 111-114, 117-146, 148-201 are rejected under 35 U.S.C. 112, first paragraph, because the specification:

A) while being enabling for a GPR-9-6 recognized by mAb 3C3 or mAb GPR96-1, or the GPR-9-6 of SEQ ID NO:2, or a GPR-9-6 that binds TECK and is at least about 90% similar to the amino acid sequence of SEQ ID NO:2, does not reasonably provide enablement for any "GPR-9-6" or any "mammalian GPR-9-6";

B) while being enabling for an agent that is an antibody to GPR-9-6 or an agent that is the chemokine TECK which binds GPR-9-6, does not reasonably provide enablement for any "agent" as broadly recited; and

C) while being enabling for a ligand which is TECK, does not reasonably provide enablement for any "ligand" as broadly recited.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

A) Claims 46-50, 78-85, 89-90, 93-95, 101-107, 130-136, 139-145, 162, 165-172 and 175-181 recite a "GPR-9-6" or a "mammalian GPR-9-6". However, the specification does not provide a sufficient enabling description of the claimed invention. A person of skill in the art is not enabled to make and use *any* "GPR-9-6" or a "mammalian GPR-9-6" as encompassed by the full breadth of the claims as currently recited. There is insufficient guidance in the specification to direct a person of skill in the art in how to make and use *any* "GPR-9-6" or a "mammalian GPR-9-6", other than a GPR-9-6 recognized by mAb 3C3 or mAb GPR96-1, the GPR-9-6 of SEQ ID NO:2, or a GPR-9-6 that binds TECK and is at least about 90% similar to the amino acid sequence of SEQ ID NO:2.

Although human GPR-9-6 was known to the skilled artisan at the time the invention was made to be a member of the chemokine receptor family, there is insufficient guidance as to which molecules other than a GPR-9-6 recognized by mAb 3C3 or mAb GPR96-1, or the GPR-9-6 of SEQ ID NO:2, or a GPR-9-6 that binds TECK and is at least about 90% similar to the amino acid sequence of SEQ ID NO:2 were also "GPR-9-6" or "mammalian GPR-9-6" molecules. Without some guidance as to the structural and functional basis that must be shared by proteins in order to be considered a "GPR-9-6" or "mammalian GPR-9-6" protein, it would require undue experimentation of the skilled artisan to make additional "GPR-9-6" or "mammalian GPR-9-6" proteins from other species. Further, without guidance as to the structure and function shared by "GPR-9-6" or "mammalian GPR-9-6" proteins from different sources, it would be highly unpredictable that any other protein could be used in the instantly recited methods.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. The scope of the instant claims encompasses any molecule that by any criteria might be argued to be a "GPR-9-6" or "mammalian GPR-9-6" protein. Without sufficient guidance as to an objective structural and functional commonality among "GPR-9-6" or "mammalian GPR-9-6", it is unpredictable as to which other proteins may be considered "GPR-9-6" or "mammalian GPR-9-6" proteins; thus the experimentation left to those skilled in the art, is unnecessarily, and improperly, extensive and undue.

B) Claims 46-47, 84-85, 89-90, 93-95, 99-109 and 117-129 recite "an agent which binds" GPR-9-6. The specification discloses antibodies and the chemokine TECK which can each bind human GPR-9-6. The specification also discloses that other "agents" which bind GPR-9-6 may be identified by screening combinatorial libraries of various compounds (e.g., specification pages 34 and 38).

However, there appears to be insufficient guidance in the specification as filed to allow one skilled in the art to conduct such screening with a reasonable expectation of success. Applicant does not appear to provide any working examples. In addition, the state of the art at the time the invention was made did not appear to recognize any "agents" that bound GPR-9-6. Although some "agents that bind" have been identified for other chemokine receptor molecules, the skilled artisan was well aware that successful design of such agents for any particular receptor did not provide a reasonable expectation of success for the design of agents that bind for any other receptors because, in general ,the design/identification of binding agents is highly unpredictable, especially in the absence of a lead compound. For example, Huang (Pharmacol. Therapeutics 2000 86:201-215) reviews in his "Introduction" on page 202 the daunting task faced by the skilled artisan in developing small molecule regulators of protein-protein interactions, and notes that the process required long periods of trial and error testing before suitable compounds could be developed.

Thus in view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification, and the breadth of the claims, it would require undue experimentation to practice the claimed invention as broadly claimed with respect to any "agent that binds" a GPR-9-6 protein.

C) Claims 49, 78, 84, 108, 111-114, 117-130, 132-146 and 148-201 recite a "ligand" of GPR-9-6. However, the specification does not provide a sufficient enabling description of the claimed invention. A person of skill in the art is not enabled to make and use *any* "ligand of GPR-9-6" as encompassed by the full breadth of the claims as currently recited. There is insufficient guidance in the specification to direct a person of skill in the art in how to make and use *any* "ligand of GPR-9-6", other than the ligand TECK.

The term "ligand of GPR-9-6" as recited encompasses *any* molecule or pathogen that binds GPR-9-6 and modulates a function of GPR-9-6. However, while the specification discloses, e.g. at pages 71-72, that TECK binds GPR-9-6; it is highly unpredictable what other ligands may also bind GPR-9-6 because the scope of the term "ligand" is extensive and the specification provides insufficient guidance as to the identity of other "ligands of GPR-9-6", besides TECK. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth.

The state of the art at the time the invention was made recognized that chemokine receptors, such as GPR-9-6, could bind multiple ligands of highly diverse structures. Zlotnik and Yoshie (Immunity 2000;12:121-127) review that chemokine receptors such as GPR-9-6 were known to interact with multiple chemokine ligands (see for example Table 1). Similarly, Mackay (Nature Immunol. 2001;2:95-101) reviews that many chemokine receptors could also bind viral (e.g. HIV, SIV) ligands and ligands comprising other intracellular parasites (e.g., bridging paragraph of pages 98-99).

Thus while "ligand of GPR-9-6" may have some notion of the activity of the molecule; there is insufficient biochemical or structural information to enable the skilled artisan to make and use the "ligand of GPR-9-6", as broadly claimed. "It is not sufficient to define the recombinant molecule by its principal biological activity, e.g. having protein A activity, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property." Colbert v. Lofdahl, 21 USPQ2d, 1068, 1071 (BPAI 1992).

Since it is unpredictable both as to which other "ligand" would bind GPR-9-6; the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

16. Claims 103, 121, 141, 157, 167, 177, 187 and 197 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the MOLT-13 cell line is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the pertinent cell line. See 37 CFR 1.801-1.809.

While it is noted that Applicant has indicated on page 34 of the specification that the MOLT-13 is available from M. Brenner at Brigham and Women's Hospital, Boston, MA; it is unclear that this cell line is in fact "readily available to the public".

Applicant is invited to make of record evidence that the MOLT-13 cell line is "readily available".

Applicant's attention is directed to In re Lundak, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR 1.801-1.809 for further information concerning deposit practice.

17. In claims 103, 121, 141, 157, 167, 177, 187 and 197, it is apparent that the MOLT-4 cell line is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the pertinent cell line. See 37 CFR 1.801-1.809.

However, it is noted that Applicant has indicated on page 34 of the specification that the MOLT-4 cell line is publicly available from the ATCC under ATCC Accession No. CRL-1582 (ATCC Cell Lines and Hybridomas, page 149, 7th edition, 1992 American Type Culture Collection, current address 10801 University Boulevard, Manassas, VA 20110-2209).

Therefore, the enablement requirement under 35 USC 112, first paragraph is considered to be fulfilled with respect to the MOLT-4 cell line.

18. In claims 80-81, 113, 133-134, 149-150, 162-171 and 182-191, it is apparent that the 3C3 antibody is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the pertinent hybridoma which produces this antibody. See 37 CFR 1.801-1.809.

It is noted that the specification in the bridging paragraph of pages 19 and 20 indicates that the hybridoma producing the 3C3 antibody was deposited with the ATCC on March 4, 1999 and assigned ATCC Accession No. HB-12653. In addition, Applicant has assured in Paper No.10 (filed 4/26/02) that the deposit was made under the terms of the Budapest Treaty and that all restrictions will be irrevocably removed upon granting of a patent.

Therefore, the enablement requirement under 35 USC 112, first paragraph is considered to be fulfilled with respect to the 3C3 antibody.

19. In claims 82-83, 114, 135-136, 151-152, 172-181 and 192-201, it is apparent that the GPR96-1 antibody is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the pertinent hybridoma which produces this antibody. See 37 CFR 1.801-1.809.

It is noted that the specification on page 20 at lines 12-27 indicates that the hybridoma producing the GPR96-1 antibody was deposited with the ATCC on March 9, 2000 and assigned ATCC Accession No. PTA-1470. In addition, Applicant has assured in Paper No.10 (filed 4/26/02) that the deposit was made under the terms of the Budapest Treaty and that all restrictions will be irrevocably removed upon granting of a patent.

Therefore, the enablement requirement under 35 USC 112, first paragraph is considered to be fulfilled with respect to the GPR96-1 antibody.

Claim Rejections - 35 USC § 112 second paragraph

20. The following is a quotation of the second paragraph of 35 U.S.C. 112.

> *The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

21. Claims 46-48, 79-85, 89-90, 94, 99-109 and 117-129 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 46-47, 84-85, 89-90, 94, 99-109 and 117-129 are ambiguous in reciting "an agent which binds thereto". As currently recited, it is unclear if the agent binds a cell expressing GPR-9-6 without necessarily binding GPR-9-6, or if the agent binds GPR-9-6. It is suggested that Applicant amend the claims to clearly indicate that the agent binds GPR-9-6, if that is the intended limitation.

For examination purposes the claims will be considered limited to an agent which bind GPR-9-6.

B) Claims 46-48, 79-83, 89 and 99-107 are ambiguous in reciting a "function of GPR-9-6" because the metes and bounds of what is a "function" of GPR-9-6 are not defined. It is suggested that Applicant amend the claims to recite particular testable functions (e.g., those recited in claim 49 or 84).

C) Claims 46, 99-109, 117-123 and 128-129 are ambiguous in reciting "modulating" because "modulating" encompasses mutually exclusive endpoints. It is suggested that Applicant amend the claims to recite a particular direction of modulation (e.g., inhibition).

D) Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

Claim Rejections – 35 U.S.C. § 102

22. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

23. Claims 46, 89-90, 93-95, 99-100, 102, 104-109, 117-118, 120, 122-123 and 126-129 are rejected under 35 U.S.C. 102(b) as being anticipated by Vicari et al. (Immunity 1997; 7:291-301, IDS #AV, see entire document), as evidenced by Zabel et al. (J. Exp. Med. 1999; 190:1241-1255, IDS # AR3).

Vicari et al. teach the chemokine TECK from both mouse and human (see e.g., Abstract). Vicari et al. teach that TECK can induce in vitro chemotaxis of the human cell line THP-1 after activation with IFNγ and can induce in vitro chemotaxis of primary mouse cells including thymocytes (see e.g., pages 294-295 "Chemotactic Activities of mTECK protein"). Vicari et al. also contact cells in vivo by administering TECK (e.g., see comment on page 296, 1st full sentence). The receptor which binds TECK on the IFNγ activated human cell line THP-1 would inherently have the amino acid sequence of SEQ ID NO:2 or a sequence at least about 90% similar.

Zabel et al. evidence that the chemokine TECK binds GPR-9-6 and promotes functions of GPR9-6 including chemotaxis and calcium flux (see entire document, e.g., Abstract and Figures 8 and 10).

When a claim recites using an old composition or structure (e.g. TECK) and the use is directed to a result or property of that composition or structure (promotion of a function of GPR-9-6 inherently expressed on the cell contacted), then the claim is anticipated. See MPEP 2112.02. Also, see Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc. 58 USPQ2d 1508 (CA FC 2001); Ex parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999).

The reference teachings thus anticipate the instant claimed invention.

Conclusion

24. No claim is allowed.

25. Claim 147 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark, whose telephone number is (703) 605-1209. The examiner can normally be reached Monday to Friday from 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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December 17, 2002

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